Exhibit A

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Melisa Miller, District Clerk
Montgomery County, Texas
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CAUSE NO. 23-04-05209

JENNIFER BRIDGES, GUARDIANS OF MEDICAL CHOICE, VICENTE SUAREZ, BREANN EMSHOFF, AMANDA LOFTON, BRETT COOK, STEFANIE MARTINEZ, DEANNA CONWAY, TAMEKA CLARK, KATHY TOFTE, DEREK TREVATHAN, DINA AMAYA, AMANDA RIVERA, MANDY SISTO, AQUARIUS GRADY, CEDRICK GREEN, N I C O L E SMITH, PAIGE THOMAS, GERARDO GARZA, CERANISE ALCINDOR, KAYLAN TIMMONS, SCOTT ANDERSON, EMILEE SMITH, SHELBY THIMONS, THOMAS MULKEY, MARIA RODRIGUEZ, AVERI REED, AMANDA CASTRO, BECKY MELCER, TANISHA HATCHET, TALISHA SMITH SHAYNA LINCOLN, KARA SHEPHERD, STACEY MARTINEZ, BRIAN MATTHEWS, ROSEMARIE ALDAYA, SANDRA ALTAMIRANO, JUDITH ANDRIKO, MARY APACWAY, DAJUANA ARMSTRONG, EDNA BARRERA, DEBRA BAUGH, LATRICIA BLANK JAMES BORJE, LAURA BOWDEN, SAVANNAH BRAZIL, JOHN BROCKUS, KATHERINE BROL, MONIKA BURY, PATRICK CHARLES, BRIAN CLEGG, SHERRY COLBERT, JOANN CRUMP-CREAMER, ZORETTA CURRY, JULIE DeTORRE, SIERRA DOCKRAY, STEPHANIE DUNLAP, J.MANUEL ELIZONDO, CELINA ELVIR, BRIAN FELGERE, ELIZABETH FLORES, REBEKA FONTENOT, MICHELLE FUENTES, ASHTON HANLEY, TARA HANSEN, STACEY HANZELKA, STARLA HAUGENATER, PHILIP HERIN, SHAUNA HERIN, JADE HERNANDEZ, LUIS HERNANDEZ, STEPHANIE HILTON, SHARON HOLLIER, WALTER INFANTES, DANA JANOCH, JASON JIMENEZ, JOHN LASSEIGNE, ASHLEE LEON-LEWIS, BENNIE LOPEZ, JAMES McCANN, ROGELIO MENDEZ, JR., KIMBERLY MIKESKA, YOLUNDA MILTON, AHMED MONTGOMERY, ROBERT MORIN, BRADY NESBIT, BOB	§	IN THE ___DISTRICT COURT Montgomery County - 284th Judicial District Court MONTGOMERY COUNTY, TEXAS

NEVENS, LINDA PICKARD, McKENLI PINKNEY, JONAE POWELL, JUAN RAMIREZ, KIMBERLY RENSI, PEEJAYE ROBINS , BETTY SAMUEL, DIANA SANCHEZ, GIOVANNI SAVANS, LEEVETRA SEALS, MARIA SERRANO, FREENIA STEWART, KARENE TANNER, KELLY TATE, MARIA TREVINO, TERAH TREVINO, CHRLES VARGHESE, BRANDI VINCENT, MATHEA VOLESKY, JENNIFER WARREN, ALEXANDRA WILLIAMS, KAREN WITT, KIDIST WOLDERGABRIEL, LATASHA WOODS, KATIE YARBER AND RICARDO ZELANTE	§
Plaintiffs,	§
V.	§
THE METHODIST HOSPITAL DOING BUSINESS AS THE METHODIST HOSPITAL SYSTEM, AND HOUSTON METHODIST THE WOODLANDS HOSPITAL, Defendants.	§

PLAINTIFFS' ORIGINAL PETITION

COME NOW, JENNIFER BRIDGES, GUARDIANS OF MEDICAL CHOICE, *et al.*, Plaintiffs herein, and file this Original Petition against Defendants THE METHODIST HOSPITAL doing business as THE METHODIST HOSPITAL SYSTEM and METHODIST HEALTH CENTERS doing business as HOUSTON METHODIST THE WOODLANDS HOSPITAL, and would show the following to this Honorable Court:

I.
PARTIES

Plaintiff, Vicente Suarez, is an adult individual residing in Montgomery County, Texas, and was previously an employee at Houston Methodist The Woodlands Hospital.

Plaintiff, Breann Emshoff, is an adult individual residing in Harris County, Texas, and was

previously an employee at Houston Methodist The Woodlands Hospital.

Plaintiff, Amanda Lofton, is an adult individual residing in Montgomery County, Texas, and was previously an employee at Houston Methodist The Woodlands Hospital.

Plaintiff, Brett Cook, is an adult individual residing in Lubbock County, Texas, and was previously an employee at Houston Methodist The Woodlands Hospital.

Plaintiff, Stefanie Martinez, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist.

Plaintiff, Deanne Conway, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist Willowbrook Hospital.

Plaintiff, Tameka Clark, is an adult individual residing in Fort Bend County, Texas, and was previously an employee at Houston Methodist Sugar Land Hospital.

Plaintiff, Kathy Tofte, is an adult individual residing in Montgomery County, Texas, and was previously an employee at Houston Methodist Willowbrook Hospital.

Plaintiff, Derek Trevathan, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist Hospital – Texas Medical Center.

Plaintiff, Dina Amaya, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist Sugar Land Hospital.

Plaintiff, Amanda Rivera, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist Baytown Hospital.

Plaintiff, Mandy Sisto, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist Willowbrook Hospital.

Plaintiff, Aquarius Grady, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist Hospital – Texas Medical Center.

Plaintiff, Cedrick Green, is an adult individual residing in Harris County, Texas, and was

previously an employee at Houston Methodist Hospital – Texas Medical Center.

Plaintiff, Paige Thomas, is an adult individual residing in Galveston County, Texas, and was previously an employee at Houston Methodist Clear Lake.

Plaintiff, Gerardo Garza, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist Hospital – Texas Medical Center.

Plaintiff, Ceranise Alcindor, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist West Hospital.

Plaintiff, Kaylan Timmons, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist Willowbrook Hospital.

Plaintiff, Scott Anderson, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist Willowbrook Hospital.

Plaintiff, Emilee Smith, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist Hospital – Texas Medical Center.

Plaintiff, Shelby Thimons, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist Willowbrook Hospital.

Plaintiff, Thomas Mulkey, is an adult individual residing in Fort Bend County, Texas, and was previously an employee at Houston Methodist Hospital – Texas Medical Center.

Plaintiff, Maria Rodriguez, is an adult individual residing in Harris County, Texas, and was previously an employee at The Methodist Hospital.

Plaintiff, Averi Reed, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist Hospital – Texas Medical Center.

Plaintiff, Amanda Castro, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist Baytown Hospital.

Plaintiff, Becky Melcer, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist Willowbrook Hospital.

Plaintiff, Tanisha Hatchet, is an adult individual residing in Fort Bend County, Texas, and was previously an employee at Houston Methodist Sugar Land Hospital.

Plaintiff, Talisha Smith, is an adult individual residing in Harris County, Texas, and was previously an employee at Houston Methodist West Hospital and Texas Medical Center.

Plaintiff, Shayna Lincoln, is an adult individual residing in Harris County, Texas and was previously an employee at Houston Methodist Hospital – Texas Medical Center.

Plaintiff, Anna Soberano-Hathorn, is an adult individual residing in Fort Bend County, Texas and was previously an employee at Houston Methodist Sugar Land Hospital.

Plaintiff, Kara Shepherd, is an adult individual residing in Harris County, Texas and was previously an employee at Houston Methodist Hospital – Texas Medical Center.

Plaintiff, Stacey Martinez, is an adult individual residing in Fort Bend County, Texas and was previously an employee at Houston Methodist Hospital – Texas Medical Center.

Plaintiff, Brian Matthews, is an adult individual residing in Galveston County, Texas and was previously an employee at Houston Methodist Clear Lake Hospital.

Plaintiff, Guardians of Medical Choice is a non- profit corporation formed to represent the combined interests of all the other Plaintiffs as a group.

Additional named Plaintiffs are adult individuals residing in Texas and were previously employees at Houston Methodist Hospital locations.

Defendant, The Methodist Hospital doing business as The Methodist Hospital System ("Methodist"), is a corporation duly authorized to conduct business within the State of Texas. Defendant may be served through its registered agent: CT Corporation System, 1999 Bryan Street,

Suite 900, Dallas, Texas 75201-3136.

Defendant, Methodist Health Centers doing business as Houston Methodist The Woodlands Hospital ("The Woodlands Hospital"), is a corporation duly authorized to conduct business within the State of Texas located at 17201 Interstate 45, The Woodlands, Montgomery County, Texas, 77385. Defendant may be served through its registered agent: CT Corporation System, 199 Bryan St., Ste. 900, Dallas, Texas 75201-3136.

II.
JURISDICTION AND VENUE

The Court has subject-matter jurisdiction under the Texas Constitution, Article V, § 8, as the amount in controversy exceeds the minimum jurisdictional limits of the court of exclusive interest. Plaintiffs seek relief that can be granted by courts of law or equity.

The court has jurisdiction pursuant to the Texas Uniform Declaratory Judgment Act, Tex. Civ. Prac. & Rem. Code §37.001 *et seq*. In addition, jurisdiction is proper because the amount in controversy satisfies the jurisdictional limits of this Court, and all parties are subject to personal jurisdiction in Texas.

Jurisdiction over attorneys' fees requested by Plaintiff herein is conferred upon this Court by Tex. Civ. Prac. & Rem. Code §37.009. Jurisdiction to award the declaratory relief requested herein is conferred upon this Court by Tex. Civ. Prac. & Rem. Code §37.004.

Venue is proper in Montgomery County, Texas pursuant to Tex. Civ. Prac. & Rem. Code §§15.002(a) and 15.032 because the cause of action arose in Montgomery County, Texas because a substantial part of the events or omissions giving rise to the claim occurred in Montgomery County, Texas and because loss occurred in Montgomery County, Texas.

III.
FACTS

On April 1, 2021, Defendants Houston Methodist and The Houston Methodist Woodlands Hospital issued a policy "requiring mandatory [Coronavirus] immunization of all covered Houston Methodist (HM) employees" despite the irrefutable fact that no licensed or EUA product existed to immunize individuals from any COVID-19 variant. The deadline set by which corporate employees who were Director level or above must be vaccinated or be

terminated from their employment was April 29, 2021. In an email to all corporate leaders on March 31, 2021, Houston Methodist CEO Marc Boom stated, "As part of Houston Methodist management, we must lead by example and get vaccinated ourselves." He went on to say, "We need you to go first-to lead by example and show our employees how important getting vaccinated is." Throughout the pandemic Marc Boom states repeatedly, "requiring the vaccine is for patient safety" yet, he chose to start with corporate management, most of whom were working remotely and had no patient facing duties. He followed with requiring nurses, doctors, and other patient facing employees to get vaccinated by June 7, 2021. In this same email, he went on to state, "When we choose to be vaccinated we are prioritizing safety and helping stop the spread and keep our patients safe. However, this statement is misleading as there was no data that showed the vaccines stopped transmission and the unassailable fact that there was not a single COVID-19 drug classified by the FDA as a Vaccine. In fact, the FDA stated in a December 11, 2020, press release announcing the authorization of Pfizer's COVID-19 vaccine that "at this time, data are not available to make a determination about how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person." Marc Boom's crystal ball was based on zero data! In an email to employees after the mandatory vaccine deadline lapsed, CEO Dr. Marc Boom stated, "I wish the number could be zero, but unfortunately, a small number of individuals have decided to not put their patients first." This passive-aggressive swipe at those who opted out of taking the experimental non-FDA approved COVID-19 vaccine extends also to the medical community at large in Houston. He went on to claim, "The employees that chose not to get vaccinated do not represent the ICARE values (Integrity, Compassion, Accountability, Respect, Excellence)

of the hospital." Many of those terminated were Covid frontline nurses who sacrificed everything for their patients. Many with prior infections already had natural immunity. We know now the vaccines did not stop transmission.

Houston Methodist Hospital Executive Vice President and Chief Information Officer, Roberta Schwartz, stated in a virtual townhall on April 15, 2021, the same day Plaintiffs were put on unpaid suspension for not taking the vaccine, stated, "Can we require visitors to be vaccinated since they can give us covid even after us being vaccinated." This clearly shows leadership did not believe in the efficacy of the vaccine but believed in its profit producing potential. Dr. Robert Phillips, Houston Methodist Physician Organization CEO, responded with, "We would if we could but we can't."

In addition, Plaintiffs (hereafter "First Amendment Plaintiffs"), Aldaya, Anderson, Apacway, Barrera, Blank, Borje, Bowden, Brazil, Brockus, Castro, Clark, Colbert, Conway, Cook, Crump-Creamer, Curry, Dockray, Dunlap, Elizondo, Emshoff, Felgere, Fontenot, Garza, Grady, Green, Hanzelka, Hernandez (Jade), Hernandez (Luz), Jimenez, Leon-Lewis, McCann, Melcer, Mendez, Milton, Montgomery, Morin, Nesbit, Nevens, Pinkney, Powell, Reed, Rivera, Robins, Rodriguez, Sanchez, Sisto, Soberano-Hathorn, Stewart, Thomas, Trevino (Maria), Trevino (Terah), Varghese, Vincent, Warren, Woldergabriel, Yarber, and Zelante claimed free exercise of religious viewpoint exemptions, which were all denied by Defendants.

IV.
DEFENDANTS' ACTIONS VIOLATE LAW AND PUBLIC POLICY OF THE STATE OF TEXAS

In Texas there is a ban on student COVID-19 vaccine mandates. On April 5, 2021, Governor Greg Abbott issued an executive order that prohibited any public or private entity

that receives public funds through any means, including grants, contracts, loans, or other disbursements of taxpayer money, from requiring a consumer, as a condition of receiving a service or entering any place or facility, to provide documentation regarding vaccination status for any COVID-19 vaccine issued under emergency use authorization. Houston Methodist violated this and continues to violate this executive order. Houston Methodist employees were required to utilize Houston Methodist doctors and health services through the System's health insurance offering. Employee were patients consuming their health care services through Houston Methodist. Houston Methodist receives state grants for research and accepts a variety of public funds through CHIP, STAR, STAR PLUS, STAR KIDS, and other Texas Medicaid managed care programs.

On July 29, 2021: Gov. Greg Abbott issued an executive order that restated language from the April 5th executive order prohibiting publicly funded entities from requiring documentation regarding vaccination status as a condition of receiving a service or entering any place or facility.

On August 25, 2021: Gov. Greg Abbott issued an executive order that restated language from the April 5th executive order but expanded the order to include COVID-19 vaccines with full FDA approval. This measure prohibits any public or private entity that receives public funds through any means from requiring a consumer to provide documentation of vaccination status for any COVID-19 vaccine.

On October 11, 2021, Texas Governor Gregg Abbott issued Executive Order GA-40 The order states that no entity, including a private business, may compel any employee or consumer to obtain a COVID-19 vaccine if that person "objects to such vaccination for any

reason of personal conscience, based on a religious belief, or for medical reasons, including prior recovery from COVID-19." Houston Methodist continues to operate in violation of this Executive Order, even denying an employed chaplain of her religious exemption request.

Therefore, the public policy of the state of Texas demands an exemption to vaccination for those who are terminated for refusing to be injected with an experimental non-FDA approved vaccine. Specifically, Defendants forced COVID-19 injection policy is contrary to the public policy of this state. As stated above, on April 5, 2021, Governor Greg Abbott issued Executive Order No. GA-35 prohibiting state agencies or political subdivisions in Texas from creating a "vaccine passport" requirement, or otherwise conditioning receipt of services on an individual's COVID- 19 vaccination status. The order also prohibited organizations receiving public funds from requiring consumers to provide documentation of vaccine status in order to receive any service or enter any place. Governor Abbott has stated, "As I've said all along, these vaccines are always voluntary and never forced." To further emphasize his position and the public policy of the state of Texas, Governor Abbott stated, "Government should not require any Texan to show proof of vaccination and reveal private health information just to go about their daily lives. That is why I have issued an Executive Order that prohibits government-mandated vaccine passports in Texas."

Thus, State of Texas policy has been made abundantly clear that individuals may not be required to either obtain vaccines or provide documentation to certify an individual's COVID-19 vaccination status.

V.

COVID-19 RESEARCH DRUG PARTICIPATION WAS ILLEGALLY REQUIRED

On December 11, 2020, the United States Food and Drug ADMINISTRATION ("FDA") issued the first emergency use authorization ("EUA") for Pfizer's BioNTech COVID-19 Investigational New Drug for the purpose of investigating the prevention of coronavirus disease 2019 ("COVID-19"). Congress mandates that an Emergency Use Authorization can only be issued under the condition that no licensed product exists to treat the unknown agent causing disease. Therefore, medical products under an EUA are legally considered to be experimental for their intended use according to the product's labeling. The experimental vaccine had only been in existence for less than a year. The first reported use of the experimental vaccine was December 14, 2020.

It is undisputed that the investigational drugs being forced upon the Plaintiffs were not licensed for any indication by the FDA. Even though the FDA granted emergency use authorization for the Pfizer/BioNTech and Moderna vaccines in December 2020, the clinical trials the FDA will rely upon to ultimately decide whether to license these and other COVID-19 experimental vaccines are still underway and are designed to last for approximately two (2) years to collect adequate data to establish if these vaccines are safe and effective enough for the FDA to approve. The abbreviated timelines for the emergency use applications and authorizations means there is much the FDA does not know about these products even as it authorizes them for emergency use, including their effectiveness against infection, death, and transmission of SARS-CoV-2, the virus that is allegedly the cause of the COVID disease. The original EUA for Pfizer did not include myocarditis or pericarditis. The latest EUA includes them both. Hence, Houston

Methodist did not know the vaccines were safe but continued to say so. Given the uncertainty about the COVID-19 experimental vaccines, the FDA requires that each dose of the experimental vaccine shall have a label that states that the product is an emergency use authorization, that the EUA is explicit that each is "an investigational vaccine not licensed for any indication" and that all "promotional material relating to the Covid-19 Vaccine clearly and conspicuously…state that this product has not been approved or licensed by the FDA but has been authorized for emergency use by FDA".

The FDA on their website has stated the following:

"FDA believes that terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirement and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564… In an emergency, it is critical that the conditions that are part of the EUA or an order or waiver issued pursuant to section 564A – those that FDA has determined to be necessary or appropriate to protect the public health-be strictly followed, and no additional conditions be imposed."

In August 2020, the Centers for Disease Control and Prevention ("CDC") published a meeting of the Advisory Committee on Immunizations and Respiratory Diseases, Dr. Amanda Cohn stated (@1:14:40):

"I just wanted to add that, just wanted to remind everybody, that under an Emergency Use Authorization, an EUA, vaccines are not allowed to be mandatory. So, early in the vaccination phase, individuals will have to be consented and they won't be able to be mandated."

In April of 2021, Marc L. Boom, in conjunction with the board of directors and executive staff, used their positions of authority to place individuals employed or conducting business with Methodist under threat of penalty should they refuse to volunteer for participation in a COVID-19 clinical research drug in violation of federal and state law. Moreover, in an attempt to coerce participation, Marc Boom threatened individuals under his care access to

living wages, benefits, and healthcare should they refuse to enter into a legally binding agreement with the federal government, an agreement that comes with significant legal and health consequences.

Houston Methodist's Board of Directors and Steering Committee members willfully violated their duties to protect the health and rights of individuals under their care by not complying with (1) their Institutional Review Board's legal obligations under identification number IRB00005005, (2) Federal Wide Assurance agreement (FWA00000438), (3) The Prep Act, (4) 21 USC §360bbb-3, (5) CDC Preferred Provider COVID-19 agreement, (6) the legal right conferred upon individuals by an act of Congress to accept or refuse the administration of an EUA drug, biologic, or medical device free from outside interference.

In 1974, Congress enacted the National Research Act. The Act led to the formalizing of Institutional Review Boards (IRB) whose purpose is to ensure that "appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research." - FDA (IRB Purpose, 2019). Houston Methodist operates under IRB number IORG0004219. Additionally, the Act formed the 'National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.' The Commission was required to establish the ethical guidelines required anytime a human is involved in a drug, biologic, or medical device that has not been licensed for general commercial marketing or used in research activities for an indication not approved according to the product's labeling. The Commission issued their findings in the Belmont Report in 1978. (The National Commission for the Protection of Human Subjects of 7 Biomedical and Behavioral Research. - Belmont Report. Washington, DC: U.S. Department of Health and Human Services,1979)

The Belmont Report declared (1) "An autonomous person is an individual capable of deliberation about personal goals and acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions…" (2) "To show lack of Respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments…" (3) "Respect for persons requires subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied." (Emphasis added).

The Belmont Report defines what those adequate standards of informed consent are as (1) "An agreement to participate in research constitutes valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence." (2) "Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance." (3) "Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate, or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable" (4) "Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject." (Emphasis added) (5) "…undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled."

To ensure individuals were not subjected to medical research abuses, Congress mandated through the Belmont Report that authorities must ensure individuals are not under outside pressures to participate in an investigational new drug prospectively. The United States Department of Health and Human Services (HHS), deriving its authority from the National Research Act, created a set of regulations to govern the ethical principles of the Belmont Report in 45 CFR 46.

45 CFR 46 "applies to all research involving human subjects...subject to regulation by any Federal department or agency" (45 CFR 46.101(a)). Research "means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102(l)). A human subject is broadly defined as (1) living (45 CFR 46.101(i)) (2) data from the human's involvement with the research is obtained, (45 CFR 46.102(e)(1)(i)), (3) the private identifiable information about the human is known. (45 CFR 46.102(e)(1)(ii)). Congress drafted broad definitions for research and subjects to comply with the recommendations of the Belmont Report, which declared that "the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects."

HHS ensured that all research activities would comply with Belmont Report's ethical requirements: (1) "Department or agency heads retain final judgment as to whether a particular activity is covered by this policy and this judgment shall be exercised consistent with the ethical principles of the Belmont Report (emphasis added) (45 CFR 46.101 C), (2) if the activity is considered exempt from the policy, then "the alternative procedures to be followed are consistent with the principles of the Belmont Report" (45 CFR 46.101(i)). In other words, there

is nowhere an investigational new drug (IND) involving an individual can go where it must not comply with the Belmont Report's ethical guidelines.

45CFR46 §116 provides authorities with the "adequate standards" of informed consent beyond that of the Belmont Report. If a government or private entity complies with the provisions of this section, then and only then have they obtained the "legally effective informed consent of the subject." Legally effective informed consent cannot be obtained if the individual is under outside pressures to participate in an IND.

45 CFR 46 applies to all federal agencies, departments, and the military (45 CFR 46.101(a)). Twenty-four federal agencies incorporated 45 CFR 46 into their regulatory framework, and through the Federal Wide Assurance (FWA) agreement, all US States and Territories comply with the Common Rule.

In 2001, HHS created the Office of Human Rights Protection, which established the Federal Wide Assurance (FWA) agreement. The FWA is an agreement by entities conducting business with HHS to comply with 45 CFR 46 and the Belmont Report's ethical guidelines. Houston Methodist Hospital assured HHS that they would not place individuals under outside pressure to participate in unlicensed medical products. Thus HHS assigned them compliance number FWA00000438, indicating their agreement was legally binding.

Congress prohibits any person from introducing a drug not licensed by the FDA into commerce (21 U.S.C. §355(a)). However, Congress created expanded access protocols to unlicensed products (21 USC Chapter 9 Subchapter V Part E) by individuals under emergency or educational conditions. Moreover, Congress explicitly stated the conditions under which an individual can access medical products under these statutes.

In 2004, Congress enacted Project Bioshield (21 USC §360bbb-3), hereafter referred to as section 564, to provide expanded access protocols to unlicensed drugs, according to the product's labeling, that may treat an unknown disease caused by a chemical, biological, radiological, or nuclear event if the HHS Secretary declares an emergency. However, section 564 does not exempt authorities from their legal obligations to comply with the ethical principles of the Belmont Report or 45 CFR 46 for any product granted Emergency Use Authorization (EUA) expanded access protocols. All EUA medical products must be classified by the FDA as experimental according to their intended use under a declared emergency (Section 564 (a)(2) (a, b)). The Secretary must "appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product." This required condition by Congress denotes research activity, and is why all EUA COVID-19 drugs are under IRBs requiring adherence to 45 CFR 46 and the ethical principles of the Belmont Report.

The Secretary may appropriate conditions (1) "on which entities may distribute the product" (2) "on who may administer the product" (3) "with respect to collection and analysis of information concerning the safety and effectiveness of the product". However, Congress was explicit in stating that "Nothing in this section provides the Secretary any authority to require a person to carry out any activity that becomes lawful pursuant to an authorization under this section." Thus, the Secretary is the only person authorized by Congress to determine the conditions under which persons may participate in the emergency medical countermeasure program. Moreover, the Secretary may authorize expanded access protocols to INDs, but he may not require any person to manufacture, distribute, store, administer, or participate in the

product's administration. (An IND means "a new drug or biological drug that is used in a clinical investigation" (21 CFR 312.3 "Investigational new drug")).

The Secretary must determine appropriate conditions under which the healthcare provider and individual will be informed of the product's risks, benefits, alternatives, and rights to accept or refuse participation in those conditions. Congress conferred the power to participate in an EUA product's administration only to the individual. In addition, Congress only conferred the right to administer an EUA product to a healthcare provider. The legal mechanism allowing both persons to participate in the process is informed consent. The individual must first be made aware of the required information. Then once the option to accept is chosen, they provide their legally effective consent to the provider, who is then empowered to administer the product legally. However, neither person is required to participate and may not be placed under a "sanction," "undue influence," "unjustifiable pressure," or "coercion" to engage in this agreement by a third-party entity having no legal authority to participate in the decision-making process.

In 2005, Congress passed the PREP Act to provide immunities for persons volunteering for "covered" activities. Accordingly, the HHS Secretary has issued COVID-19 PREP Act declaration 85 FR 15198. Due to immunities granted under the PREP Act, Congress made explicit that all persons engaged in activities under an emergency declaration must be only under conditions of voluntary participation: "The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure are educated with respect to contraindications, the voluntary nature of the program…" (42 U.S. Code §247d-6e(c)).

Congress established voluntary conditions for all emergency countermeasure programs due to immunity clauses. Suppose an individual is given advance notice that their involvement might incur an injury, and, in fact, an injury does occur. In that case, courts agree that their prohibition to seek judicial redress is justified because they chose to volunteer out of their free will and voluntary consent despite the known inherent dangers. The Supreme Court has held that the right to informed consent and to refuse unwanted medical treatment is "deeply rooted in this Nation's history and constitutional traditions." See Washington v. Glucksberg, 521 U.S. 702, 725 (1997); Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261, 269 (1990) ("The principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions"). This Court has also held that the right to informed consent and to refuse medical treatment is a fundamental right.

Federal funds may not be expended for research activities for civilians (45 CFR 46 §122) or the military (10 USC §980) if the legally effective informed consent of the individual is not obtained in advance. The United States government purchased all COVID-19 vaccines from manufacturers and has become the sponsor (21 CFR 312.3 "Sponsor") of the clinical research activity. To ensure its legal obligations are met, the executive branch declared that no person might administer the drug without first signing the COVID-19 Preferred Provider Agreement with the CDC. (How to Enroll as a COVID-19 Vaccination Provider website 01/28/2023). The agreement requires all practitioners administering the vaccine: (1) "must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative" to comply with informed consent requirements, (2) "Organization must report

moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS)," denoting research activities, (3) "Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine," (4) "Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws. "Under Constitutional obligations to comply with laws passed by Congress, the federal government's executive branch established the COVID-19 EUA guidelines that Marc Boom and the executive staff at Houston Methodist voluntarily agreed to adhere to.. The executive branch of the federal government is prohibited from requiring Houston Methodist to participate in any COVID-19 EUA activity. Additionally, Congress also prohibits Houston Methodist from requiring individuals under their authority to participate in the administration of a COVID-19 EUA drug outside of their free will and voluntary consent.

"Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called 'off-label' uses – i.e., any use not specified in an application and approved by FDA." (Justice Department Announces Largest Health Care Fraud Settlement in Its History, 2009). Investigational new drugs do not have a legal indication and, therefore may not be legally promoted for any indication. Therefore, when Houston Methodist Hospital unlawfully required employees to participate in a COVID-19 Vaccine, the order was physically and legally impossible to comply with because no COVID-19 drug classified by the FDA as a "Vaccine" exists in commerce for general commercial marketing (emphasis added).

Moreover, Houston Methodist treated an unlicensed drug for legal purposes as if the FDA had licensed the drug.

To date, only COVID-19 INDs have been distributed into commerce: (1) Pfizer BioNTech COVID-19 Vaccine 19736 (IND assigned application identification number) (2) Janssen IND 22657 (3) Moderna IND 19745 (4) Novavax IND 22430. A clinical investigation is synonymous with medical experimentation and "means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice" (21 CFR 312.3 "Clinical investigation"). Clinical drugs used under research activities irrespective of expanded access protocol authority require adherence to IRB oversight, per 45 CFR 46, and the Belmont Report. Houston Methodist hospital conditioned participation of Plaintiffs upon them volunteering for clinical drug participation in violation of federal and state law. Moreover, Houston Methodist coerced individuals into participating in a legally binding agreement outside of its authority and in defiance of federal and state laws, and its own federal agreements with HHS and CDC. In conclusion:

(1) Houston Methodist subjected individuals, under threat of penalty, to clinical research drug participation in violation of federal and state laws, agency regulations, and contractual obligations (e.g., FWA, IRB, Covid CDC contract). These items denote "duties" of management for the protection of the Plaintiffs.

(2) Persons engaging in an EUA product must do so by providing their informed consent. That consent means (a) they agree to assume greater inherent risks, (b) they agree to forfeit litigation rights for sustained injuries under the PREP Act, (c) they will allow their private

identifiable information and data collected about their involvement with the EUA product to be utilized by researchers for unknown purposes for eternity under 45 CFR 46 protocols, (d) they agree to receive the product in spite of the known risks of the product. These requirements denote a legally binding agreement between the individual, healthcare provider, and federal, state, and local governments (due to PREP act declaration). Houston Methodist coerced individuals to participate in an agreement having significant legal consequences without informing them of those legal conditions. Moreover, they did not ask individuals if they would like to volunteer, they emphatically informed them that they must volunteer or lose access to living wages.

(3) The PREP Act requires all participants to volunteer for program participation. Houston Methodist interfered with the PREP Act's legal obligations of the federal government and the State of Texas to ensure all individuals participate under voluntary conditions.

(4) The HHS Secretary is the only person authorized by Congress to establish the conditions under which individuals can access EUA investigational drugs and those conditions are outlined in the "Scope of Authorization" as established in the EUA letter. Houston Methodist engaged in fraud by amending the Scope of Authorization for each EUA drug when they required participation by those under their authority. Houston Methodist may not require that which Congress prohibits.

(5) Houston Methodist engaged in fraudulent misrepresentation by "promoting" available EUA drugs as being "safe" and "effective" which is prohibited by 21 CFR 312.7(a) in an effort to coerce drug participation.

(6) Houston Methodist infringed upon the rights of individuals to accept or refuse an EUA product. The Right to accept or refuse is a power individuals hold exclusively with which no third party may interfere.

(7) Houston Methodist interfered with the legal obligations of healthcare providers to obtain the legally effective informed consent of individuals participating in the emergency countermeasure program. Houston Methodist did not obtain the legally effective informed consent of ANY employee to include those who agreed to participate in the product.

(8) Houston Methodist issued a mandate that was physically and legally impossible to comply with. The FDA has not licensed a COVID-19 Vaccine that was also introduced into commerce for general commercial marketing.

(9) Houston Methodist applied "undue influence" when paying employees $500, $1,000, and paid time off for participating in an EUA product.

Plaintiffs have been terminated from their jobs and others are in imminent and immediate danger of being terminated from their jobs for exercising their federally protected right to refuse voluntary participation in an investigational new drug without incurring a penalty or losing a benefit to which they are otherwise entitled. The Due Process clause of the Fourteenth Amendment substantively protects certain fundamental rights. Among these are the right to be free from unjustified intrusions into the body, Ingraham v. Wright, 430 U.S. 651, 673 (1977), the related right to refuse unwanted medical treatment, Rennie v. Klein, 653 F.2d 836, 844 (3d Cir. 1981), and as we decide today, the right to sufficient information to intelligently exercise those rights." White v. Napoleon, 897 F.2d 103, 111 (3d Cir. 1990). As a result, this right now deserves strict or heightened scrutiny. Glucksberg, at 720, 722 ("heightened protection" of substantive due

process applies to "concrete examples involving fundamental rights found to be deeply rooted in our legal tradition."). Since the Due Process Clause protects the free exercise of informed consent to medical treatment, policies that single out the exercise of informed consent for sanction violate that freedom. Defendants' policy burdens the exercise of informed consent by coercing employees to take a vaccine they do not want with the consequence of terminating their employment if they chose not to vaccinate.

VI.

FREE EXERCISE CLAUSE OF THE FIRST AMENDMENT TO THE UNITED STATES CONSTITUTION PROHIBITS DEFENDANTS FROM ABRIDGING PLAINTIFFS' RIGHTS TO FREE EXERCISE OF RELIGION.

The Free Exercise Clause of the First Amendment to the United States Constitution prohibits Defendants from abridging Plaintiffs' rights to free exercise of religion. First Amendment Plaintiffs have sincerely held religious beliefs that compel them to refuse vaccination with abortion-connected vaccines. The vaccine mandate, on its face and as applied, targets First Amendment Plaintiffs sincerely held religious beliefs by requiring the revocation of religious exemptions previously granted to them or by prohibiting them from seeking and receiving exemption and accommodation for their sincerely held religious beliefs from their employer. The vaccine mandate, on its face and as applied, impermissibly burdens First Amendment Plaintiffs sincerely held religious beliefs, compels them to abandon their beliefs or violate them under coercion, and forces First Amendment Plaintiffs to choose between their religious convictions and their employer's patently unconstitutional value judgment that their religious beliefs are of no account and cannot be considered.

The vaccine mandate, on its face and as applied, places First Amendment Plaintiffs in an irresolvable conflict between compliance with the mandate and their sincerely held religious beliefs. The vaccine mandate, on its face and as applied, puts substantial pressure on First Amendment Plaintiffs to violate their sincerely held religious beliefs or face loss of their occupations, professional standing, licenses, reputations, and ability to support their families. The vaccine mandate, on its face and as applied, thus targets First Amendment Plaintiffs' religious beliefs for disparate and discriminatory treatment. There is no legitimate, rational, or compelling interest in the vaccine mandate's exclusion of exemptions and accommodations for sincerely held religious beliefs, especially given that the available COVID-19 vaccines are clearly failing to prevent transmission or infection, so that "booster shots" are now being promoted. The vaccine mandate is not the least restrictive means of achieving an otherwise permissible government interest, which could be achieved by the same protective measures (masking, testing, quarantining, etc.) already being required of the vaccinated and the unvaccinated alike. The vaccine mandate, on its face and as applied, has caused, is causing, and will continue to cause irreparable harm and actual and undue hardship to First Amendment Plaintiffs from violation of their sincerely held religious beliefs and the occupational, professional, social and economic consequences pleaded above. First Amendment Plaintiffs have no adequate remedy at law to prevent the continuing violation of their constitutional liberties and sincerely held religious beliefs.

VII.

PRAYER

Plaintiffs request the Court issue declaratory relief under Tex. Civ. Prac. & Rem. Code §§

37.004 and 37.006 that federal laws and regulations do not permit Defendants to coerce an employee to accept an FDA unapproved vaccine on penalty of termination or other sanctions. Accordingly, Plaintiffs request a declaration that Defendants 'above-described COVID-19 vaccination policy is invalid. Plaintiffs further request: that any Plaintiffs who were involuntarily terminated due to this policy be given an opportunity to be reinstated, as well as backpay to their date of termination; and award Plaintiffs costs of suit pursuant to TexasUniform Declaratory Judgments Act, section 37.009; exemplary and punitive damages, and for such other and further relief that may be awarded at law or in equity.

Respectfully submitted,

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Automated Certificate of eService

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Roger Borgelt on behalf of Roger Borgelt
Bar No. 02667960
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Envelope ID: 74481289
Filing Code Description: Petition
Filing Description: Plaintiff's Original Petition
Status as of 4/11/2023 11:01 AM CST

Associated Case Party: Guardians of Medical Choice

Name	BarNumber	Email	TimestampSubmitted	Status
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